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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,667	01/19/2000	Stephen Donovan	D-2875	6119

7590

07/09/2004

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Irvine, CA 92618

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,667

Applicant(s)

DONOVAN, STEPHEN

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 77-80 is/are allowed.
- 6) ☒ Claim(s) 69-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 69-80 are pending.

Applicants' response filed April 23, 2004 is acknowledged, and has been fully considered. Claims 69-80 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 102

2. The previous rejection of claims 69-80 under 35 U.S.C. 102(e) as being anticipated by Quinn *et al.* (U.S. Patent 6,632,440 B1), is withdrawn in view of applicant's response at pages 2-4 in the response filed April 23, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 69-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 69-76 are indefinite as to whether the modified clostridial neurotoxin contains the H_C domain (a binding domain to motor neurons) since the claim only indicates the clostridial neurotoxin is modified by covalently coupling to substance P, however, the claim also indicates the clostridial neurotoxin no longer binds to neurotoxin receptors at a neuromuscular junction with the same affinity as a native clostridial neurotoxin, thus it is not clear how the binding affinity of the modified clostridial neurotoxin is less than the native clostridial neurotoxin if H_C

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domain is still present in the modified clostridial neurotoxin, and how substance P affects the binding affinity of the modified clostridial neurotoxin to the receptors. Claims 70-76 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

A proposed amendment to claims 69, 70, 74 and 75 is suggested.

69. (Currently amended) An agent for treating pain comprising a modified clostridial neurotoxin, wherein the modified clostridial neurotoxin [has been modified] is obtained by removing an H_C domain from a native clostridial neurotoxin and covalently coupling to substance P [to the clostridial neurotoxin] so that the modified neurotoxin no longer binds to neurotoxin receptors at a neuromuscular junction with the same affinity as [a] the native clostridial neurotoxin.

70. (Currently amended) The agent of claim 69 wherein the clostridial neurotoxin is [produced by] obtained from an organism selected from the group consisting of Clostridial beratti, Clostridial butyricum, Clostridial botulinum and Clostridial tetani.

74. (Currently amended) The agent of claim 73 wherein the H_N is [produced by] obtained from selected from the group consisting of Clostridial beratti, Clostridial butyricum, Clostridial botulinum and Clostridial tetani.

75. (Currently amended) The agent of claim 73 wherein the L chain is [produced by] obtained from an organism selected from the group consisting of Clostridial beratti, Clostridial butyricum, Clostridial botulinum and Clostridial tetani.

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Conclusion


4. Claims 69-76 are rejected, it appears claims 77-80 are free of art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

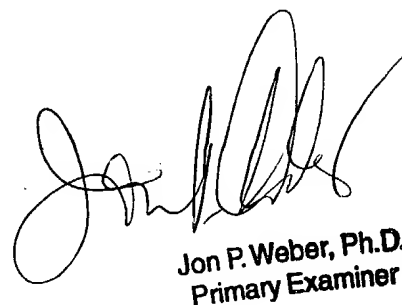
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CMK
July 1, 2004



Jon P. Weber, Ph.D.
Primary Examiner